

Robert B. Stroube, M.D., M.P.H
Virginia State Health Commissioner
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Mr. Chairman and distinguished members of the House Government Reform Committee, my name is Dr. Robert Stroube. I am the State Health Commissioner for the Virginia Department of Health (VDH), and I am honored to be testifying before you today. I would like to thank the Chair and the subcommittee members for convening this hearing regarding the recent developments concerning the U.S. influenza vaccine supply.

As State Health Commissioner I serve as the principal advisor to Virginia Governor Mark Warner, Virginia Secretary of Health and Human Resources Jane Woods and the Virginia General Assembly on a wide range of public health issues. I was appointed by Governor Warner in 2001. I have served Virginia in virtually every leadership position within public health at the state and local level during my career of over 31 years.

I earned a Doctor of Medicine degree from the Medical College of Virginia, a Masters in Public Health from the Johns Hopkins University, and an undergraduate degree from the College of William and Mary. I am a specialist in preventive medicine and certified by the American Board of Preventive Medicine.

The recent flu vaccine shortage is creating a serious challenge for public health. The present system of vaccine production and distribution is incapable of effectively responding to the current demand for the vaccine let alone a large scale flu outbreak or pandemic. It is imperative that the federal government take steps now to improve our current flu vaccine production and distribution system.

In Virginia, the health department ordered about 110,000 doses of flu vaccine from manufacturer Chiron, which we will not receive. This is almost all of the flu vaccine that we typically provide to adults through our 119 local health departments.

Not having this vaccine will mean that many people – especially those at high risk for flu complications – will not be able to count on their local health department for a flu shot this year.

At this time, we expect to only receive about 11,000 doses of adult flu vaccine. But this is just a drop in the bucket compared with the amount of flu vaccine that is needed for those people in our communities who are most vulnerable to serious complications from the flu.

Any flu vaccine available through our local health departments will be provided to those people who are in the high risk priority groups recommended by the Advisory Committee on Immunization Practices (ACIP) this past Tuesday.

The flu vaccine shortage hopefully will not impact the more than 115,000 doses of flu vaccine we have ordered from Aventis for children enrolled in the Vaccines for Children

(VFC) program. This program is for un-insured and under-insured children, Native American children, and those on Medicaid.

But the health department provides a very small proportion of the flu vaccine that is typically provided to the public. Most vaccine is provided by the private sector.

The biggest difficulty is determining how much flu vaccine is available in the private sector within our state and how to advise our at-risk populations on where to find any available vaccine. We do not have an instantaneous way of tracking flu vaccine availability in the private sector, and we do not have any legal authority to redirect flu vaccine in the private sector.

We are making every effort to encourage the medical community to follow the ACIP recommendations and prioritize the available supply for people in the priority groups identified. We have distributed information from the U.S. Centers for Disease Control and Prevention to the health care community through our Health Alert Network.

In addition to our outreach to the medical community, we distributed a statewide press release encouraging the prioritization of available flu vaccine, we have conducted numerous media interviews, and we have taken hundreds of phone calls from citizens. We are providing people the best information we have available regarding this developing situation.

This serious situation is compounded by the fact that we have gone to great lengths over the past few years to educate the public about the importance of getting their flu shot each year. We have not only encouraged people in the high risk groups to get their flu shot, but more and more it is being encouraged for all people.

We had just launched our statewide education efforts for this year – prior to receiving the unexpected news about Chiron. Our education efforts have now been undermined again due to this situation. For example, we had to cancel our annual “Vaccinate and Vote” campaign, which targets the vaccination of high risk individuals on Election Day.

And, six upcoming smallpox vaccination dispensing exercises for our bioterrorism preparedness program are now on hold because the flu vaccine was going to be provided to volunteers participating in those exercises.

This current situation follows similar problems we had last year when we ran out of flu vaccine at the height of the season. Last year, VDH administered more than 160,000 doses of flu vaccine to the public, which is more than double the number of flu shots than is typically provided through our local health departments. During a typical year the health department provides about 70,000 doses of flu vaccine.

When we ran out of the flu vaccine last year, many high-risk patients went without vaccine, parents could not get young children vaccinated, and healthcare providers could not vaccinate their staff. Attempting to prioritize vaccine to high-risk patients was a local health department nightmare. In some cases security was needed to maintain control of demanding patients.

Now Virginia and all the other states are faced with the difficulties of prioritizing a limited supply of flu vaccine again, even more limited than last year, and we can anticipate that many people will go unvaccinated this year.

As you know, only three companies are licensed in the U.S. to produce the flu vaccine. Chiron was expected to provide about half of the flu vaccine supply for the U.S. this year. Aventis is the only other company that produced the flu vaccine provided by injections. The third company produces the live attenuated nasal flu vaccine, which is not targeted for high-risk patients.

As I stated earlier this year when I testified before this committee, Congress needs to support the development of a more reliable vaccine production and distribution process. The current year-long process is incapable of meeting increasing vaccine demands or timely adjustments to vaccine formulation. The nation's influenza program must include a comprehensive and critical look at all aspects of the system including production and distribution of vaccine.

The current situation and our experience over the past few years cause concern regarding our ability to effectively address an influenza pandemic in the U.S. VDH has an influenza pandemic response plan, but that plan cannot be carried out without having an adequate supply of vaccines and anti-viral medications. We must rely on the federal government to assure this.

In Virginia alone, we estimate that during an influenza pandemic there could be more than 1.3 million outpatient visits, over 28,000 hospitalizations, and over 6,200 deaths in a 12 week period. The thought of these statistics alone are enough to make improving the flu vaccine production and distribution system a high priority.

It is time for the federal government to become more involved in the manufacturing process of the flu vaccine. We cannot get by with just two manufacturing companies providing the flu vaccine that is targeted for our high risk populations.

Given the estimated 36,000 people that die each year in the U.S. due to flu— I believe addressing the flu vaccine production and distribution problem should be a high priority for Congress.

Government must support improvements of the vaccine production process and consider ways of ensuring that enough flu vaccine is available.

Thank you for this opportunity to speak with you today. I would be pleased to answer any questions you may have.